

**DETAILED ACTION**

1. Claims 36-44 canceled.
2. Claims 1-35 amended.
3. Claims 1-35 of the US Patent Application No. 10/582,945 filed 06/15/2006 are examined on the merits.

***Response to Arguments***

4. Applicant's arguments filed 03/04/2008 have been fully considered but they are not persuasive.

With regards to claims 1 and 27, Applicants argue that Lee reference does not teach "organizing means configured to organize the line set such that no part of the line set extends across another part of the line set" as recited in independent claim 1.

However, Lee teaches the apparatus comprising all the limitations of organizing means introduced by Applicants and solving the same problem (organizing medical tubes at substantially the same level in predetermined position), and therefore is fully capable of performing the same function as claimed by Applicants.

Applicants further argue that the apparatus of Lee is not adapted to be used in "a package", and especially not in a package for use in a package for use in a peritoneal dialysis treatment", as recited in claim 1. However, Lee teaches the apparatus comprising all the limitations of organizing means introduced by Applicants and solving the same problem (organizing medical tubes at substantially the same level in predetermined position), and

therefore is fully capable of performing the same function as claimed by Applicants, what reads on to be adapted.

***Claim Rejections - 35 USC § 103***

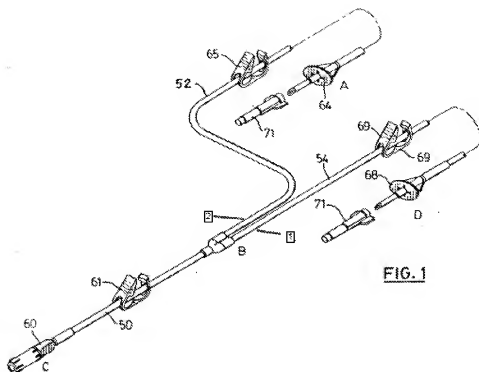
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 6-12, 18, 19, 21-26, 27-19, 31, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885).

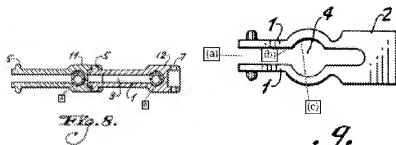
7. In Re claim 1, Dadson discloses a device for use in a peritoneal dialysis treatment, wherein the package includes a line set which comprises a first tubular line element 54, a second tubular line element 52, and elements 60, 61, 65, 69 connected to the tubular line elements 54 and 52 (See Fig. 1).

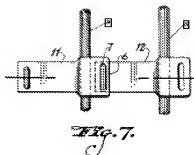
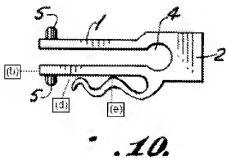
According to one of the definitions the package is a number of different components to constitute a single item. As such the device of Dadson is considered to be a package.



Dadson does not expressly disclose the organizing means connected to both first and second tubular elements and arranged to organize the line set such that no part of the line set extends across another part of the line set.

Lee teaches that it is known to use an organizing means connected to both first A and second B tubular elements and fully capable of being arranged to organize the line set such that no part of the line set extends across another part of the line set (See Figs. 7-10).





It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode.

8. In Re claim 2, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means is arranged to organize the whole line set at substantially the same level.

Lee teaches that it is known to make the organizing means arranged to organize the whole line set at substantially the same level (See Figs. 7-10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with an organizing means, as taught by Lee because such modification would provide a set being portable.

9. In Re claim 3, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means arranged to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements.

Lee teaches that it is known to make the organizing means fully capable of being arranged to organize the line set such that no part of the first and second tubular line elements is in contact with another part of the first and second tubular line elements (See Figs. 8, 9, and 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means arranged to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, as taught by Lee because such modification would prevent tubing from the mechanical damage during the storing the package.

10. In Re claim 4, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means arranged to organize the line set in a spiral-shaped state.

Lee teaches the organizing means fully capable of being arranged to organize the line set in a spiral-shaped state (See Figs. 7 and 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means arranged to organize the line set in a spiral-shaped state, as taught by Lee in order to make the package portable.

11. In Re claim 6, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means comprising the holding member configured to hold at least one portion of the first tubular line element in a predetermined position in relation to a portion of the second tubular line element.

Lee teaches the organizing means comprising the holding member configured to hold at least one portion of the first tubular line element A in a predetermined position in relation to a portion of the second tubular line element B (See Figs. 7 and 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means comprising the holding member, as taught by Lee in order to prevent unpredictable moving of the tubing elements.

12. In Re claim 7, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means comprising the holding member arranged to perform said holding in a detachable manner.

Lee teaches the organizing means comprising the holding member performing the holding in a detachable manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the package of Dadson with the organizing means comprising the holder arranged to organize the line set in a detachable manner, as taught by Lee in order to simplify operation the device.

13. In Re claim 8, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means comprising the holding member further comprising a first elongated recess, restricted by at least one resilient jaw-shaped member, said resilient jaw-shaped member being provided with at least one concavity for holding detachable said portion of the first tubular line element.

Lee teaches the organizing means comprising the holding member further comprising a first elongated recess (a), restricted by the resilient (Col. 3, ln. 47) jaw-shaped member (b) being provided with the concavity (c) for holding detachable the portion of the tubular member (See Fig. 9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson with the organizing means comprising the holding member further comprising a first elongated recess, restricted by the resilient jaw-shaped member being provided with the concavity for holding detachable the portion of the tubular member, as taught by Lee in order to improve the reliability of the holding the tubular element by the holding member.

14. In Re claim 9, Dadson discloses the claimed invention discussed above, as applied to claim 6 above, but does not disclose the organizing means wherein the holding member is configured to hold at least one portion of the first tubular line element and the at least one portion of the second tubular line element, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the first and second tubular line elements have a substantially parallel extension in the vicinity of the holding member.

Lee teaches the organizing means wherein the holding member is configured to hold at least one portion of the first tubular line element A and at least one portion of the second tubular line element B, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in

relation to each other, such that the first and second tubular line elements have a substantially parallel extension in the vicinity of the holding member (See Fig. 7).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of holding member configured to hold at least one portion of the first tubular line element and the at least one portion of the second tubular line element, said at least one portion of the first tubular line element and said at least one portion of the second tubular line element being configured in a predetermined position in relation to each other, such that the first and second tubular line elements have a substantially parallel extension in the vicinity of the holding member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide device with the type of holding member that is known to be suitable for holding tubular elements in a predetermined position substantially parallel to each other.

15. In Re claim 10, Dadson discloses the claimed invention discussed above, as applied to claim 7, but does not disclose the organizing means wherein the holding member is configured to hold fixedly a second connector, said second connector being mounted to an end of the second tubular line element.

Lee teaches the organizing means wherein the holding member is fully capable to hold fixedly a connector being mounted to an end of the second tubular line element, since the organizing means can comprise the unlimited quantity of clips (holding members) comprising the concavity (c) for holding detachable the portion of the tubular member (See Figs. 7-10).



All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of holding member configured to hold fixedly a connector being mounted to an end of the tubular line element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide device with the type of holding member that is known to be suitable for holding fixedly a connector being mounted to an end of the tubular line element.

16. In Re claim 11, Dadson discloses the claimed invention discussed above, but does not disclose the organizing means wherein the holding member comprises a hole extending through the holding member for receiving said connector.

Lee teaches the organizing means wherein the holding member comprises a pocket 4, which is a variation of the hole, and fully capable of receiving the connector mounted to the end of the tubular line element (See Figs. 8-10).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of the holding member comprising the hole for receiving the connector mounted to the end of the tubular line element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the holding member of Lee to the device of Dadson in order to provide the device with the type of holding member that is known to be suitable for holding the connector mounted to the end of the butulare line element.

17. In Re claim 12, Dadson discloses the line set comprising a drain bag, and the line set is connected to the drain bag (See Col. 6, ln. 14).
18. In Re claim 18, Dadson discloses the package wherein the package comprises a drain bag and the line set is connected to the drain bag via connector 68 positioned at an outer periphery of the line set (See Col. 6, ln. 7-9; Fig. 1).
19. In Re claim 19, Dadson discloses the package wherein the package comprises a solution bag and the line set is connected to the solution bag (Col. 6, ln. 60, 61; Col. 7, ln. 16-18).
20. In Re claim 21, Dadson discloses the package wherein the line set is connected to the solution bag via connector 64 positioned at an outer periphery of the line set (See Col. 6, ln. 7-9; Fig. 1).
21. In Re claim 22, Dadson discloses the package wherein the solution bag is filled with a dialysate solution (Col. 6, ln. 60, 61).
22. In Re claim 23, Dadson discloses the package wherein the line set comprises a third connector 60 connectable to a patient connector (See Col. 6, ln. 3-5; Fig. 1).
23. In Re claim 24, Dadson discloses the package wherein the third connector 60 is configured in a space at an inner periphery of the line set (See Fig. 1).
24. In Re claim 25, Dadson discloses the package wherein the line set comprises a component in the form of at least one flow organizer 65, 68 (Fig. 1) fully capable of being arranged to provide a space sufficient for the flow organizer such that the flow organizer does not load on any part of the first and second tubular line elements.
25. In Re claim 26, Dadson discloses the package wherein the package comprises a wrapping for encasing the line set (Col. 5, ln. 61, 62), since in accordance with the definition the package is

“a wrapped or boxed object” (See The American Heritage® Dictionary of the English Language, Fourth Edition), what reads on comprises a wrapping.

26. In Re claim 27, Dadson discloses the method for manufacturing of a package for use in a peritoneal dialysis treatment, wherein the package including a line set, which comprises a first tubular line element, a second tubular line element and elements 60, 61, 65, 69 connected to the tubular line elements 1 and 2 (See Abstract, ln. 1-10; Fig. 1).

Dadson does not expressly disclose the step of organizing the line set such that no part of the line set extends across another part of the line set.

Lee teaches that it is known to use an organizing means to organize the line set such that no part of the line set extends across another part of the line set (See Figs. 8, 9, and 10).

Since the organizing means has been disclosed by Lee as provided, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson with the step of organizing the line set, as taught by Lee because such modification would provide the organizing of the tubing package for use in a peritoneal dialysis treatment in the safety mode.

27. In Re claim 28, Dadson discloses the claimed invention discussed above, but does not disclose the method characterized by the step of organizing the whole line set at substantially the same level.

Lee teaches that it is known to use the organizing means capable to organize the whole line set at substantially the same level (See Figs. 8, 9, and 10).

Since the organizing means capable to organize the whole line set at substantially the same level has been disclosed as provided, it would have been obvious to one having ordinary

skill in the art at the time the invention was made to modify the method of Dadson with the step of organizing the whole line set at substantially the same level, as taught by Lee because such modification would provide a set being portable.

28. In Re claim 29, Dadson discloses the claimed invention discussed above, but does not expressly disclose the method characterized by the step of organizing the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements.

Lee teaches that it is known to use the organizing means capable to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements (See Figs. 8, 9, and 10).

Since the organizing means capable to organize the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson with the step of organizing the line set such that no part of the tubular line elements is in contact with another part of the tubular line elements, as taught by Lee because such modification would prevent tubing from the mechanical damage during the storing the package.

29. In Re claim 31, Dadson discloses the claimed invention discussed above, but does not expressly disclose the method including the step of organizing the line set by means of a holding member being configured to hold at least one portion of the first tubular line element in a predetermined position, in relation to a portion of the second tubular line element.

Lee teaches the organizing means comprising the holding member configured to hold at least one portion of the first tubular line element A in a predetermined position in relation to a portion of the second tubular line element B (See Figs. 7 and 8).

Since the organizing means capable to hold one portion of the tubular line element in a predetermined position in relation to another tubular line element, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson with the step of organizing the line set by means of a holding member being configured to hold at least one portion of the first tubular line element in a predetermined position, in relation to a portion of the second tubular line element, as taught by Lee in order to prevent unpredictable moving of the tubing elements.

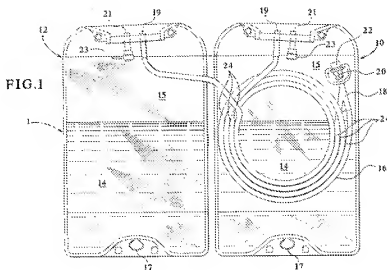
30. In Re claim 34, Dadson discloses the package wherein the package comprises a wrapping for encasing the line set (Col. 5, ln.61, 62), since in accordance with the definition the package is “a wrapped or boxed object” (See The American Heritage® Dictionary of the English Language, Fourth Edition), what reads on comprises a wrapping.

Since the package comprising the wrapping disclosed as provided, it means the step of providing the package with a wrapping has been disclosed.

31. Claims 5, 13, 15-17, 20, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885) and further in view of Keilman (US 5,820,582).

32. In Re claim 5, Dadson in view of Lee disclose the claimed invention, as applied to claim 1 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein at least one tubular lane element is pre-shaped to extend along a desired path.

Keilman teaches the system used for a peritoneal dialysis procedure (See Abstract, In. 4, 5), wherein tubular lane elements are pre-shaped to extend along a desired path (See Fig. 1).



All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of tubing packaged in the pre-shaped form. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the tubing packaged in the pre-shaped form of Keilman to the device of Dadson/ Lee in order to provide device with the tubing packaged in the pre-shaped form.

33. In Re claim 13, Dadson in view of Lee disclose the claimed invention, as applied to claim 1 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the first and second tubular line elements are manufactured of PVC.

Keilman teaches the system used for a peritoneal dialysis procedure (See Abstract, ln. 4, 5), wherein tubular line elements are manufactured of PVC (See Col. 6, ln. 30-32).

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of tubing for dialysis procedure made of PVC. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the PVC tubing of Keilman to the device of Dadson/ Lee in order to provide device with the tubing made of material that is known to be suitable for tubing set used for dialysis procedure.

34. In Re claim 15, Dadson in view of Lee disclose the claimed invention, as applied to claim 12 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is foldable to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag.

Keilman teaches the drain bag constructed of flexible plastic material (Col. 2, ln. 19, 20) and, consequently, fully capable of being folded in the claimed manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the flexible bag foldable to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag, as taught by Keilman in order to make the package portable.

35. In Re claims 16 and 17, Dadson in view of Lee and further in view of Keilman disclose the claimed invention, , but do not expressly disclose the package for use in a peritoneal dialysis

treatment, wherein the holding member is arranged to detachably engage one of said first and second folded parts of the drain bag, and wherein the holding member comprises a second recess restricted by at least one resilient jaw-shaped member, said jaw-shaped member is provided with at least one protruding member for engaging detachably the edge area.

Lee teaches the holding member comprising the recess (d) restricted by the resilient jaw-shaped member (b), and protruding member (e) (See Fig. 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee / Keilman with the holding member, as taught by Keilman, since Keilman discloses substantially the same structure, as that claimed by applicant, the structure is fully capable of performing the claimed function of the holding member being arranged to detachably engage the folded part of the drain bag.

36. In Re claim 20, Dadson in view of Lee disclose the claimed invention, as applied to claim 12 above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is applied on the solution bag.

Keilman teaches the system, wherein the drain bag is applied on the solution bag (See Col. 2, ln. 3, 10-13; Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the drain bag is applied on the solution bag, as taught by Keilman in order to form the package is such a manner to substantially reduce packaging size requirements and to simplify the packaging procedure.



37. In Re claim 30, Dadson in view of Lee disclose the claimed invention, as applied to claim 27 above, but do not expressly disclose the method for use in a peritoneal dialysis treatment, including the step of organizing the line set in a spiral shaped state.

Keilman teaches the line set provided in a spiral shaped state (See Fig. 1).

Since the line set organized in a spiral shaped state has been disclosed as provided, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Dadson/ Lee with the step of organizing the line set in a spiral shaped state, as taught by Keilman because such modification would provide the compact packaging of the line set.

38. In Re claim 32, Dadson in view of Lee disclose the claimed invention, as applied to claim 27 above, but do not expressly disclose the method, the steps of folding the drain bag to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag.

Keilman teaches the drain bag constructed of flexible plastic material (Col. 2, ln. 19, 20) and, consequently, fully capable of being folded in the claimed manner.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the steps of folding the drain bag to form first and second folded parts and wherein the line set configured in the package between the first and second folded parts of the drain bag, as taught by Keilman in order to make the package portable.

39. In Re claim 33, Dadson in view of Lee disclose the claimed invention, but do not expressly disclose the method including the step of applying the drain bag on the solution bag.

Keilman teaches the system, wherein the drain bag is applied on the solution bag (See Col. 2, ln. 3, 10-13; Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the step of applying the drain bag on the solution bag, as taught by Keilman in order to form the package in such a manner to substantially reduce packaging size requirements and to simplify the packaging procedure.

40. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885), as applied to claim 12 above, and further in view of Maasola (US 4,772,497).

Dadson in view of Lee disclose the claimed invention discussed above, but do not expressly disclose the package for use in a peritoneal dialysis treatment, wherein the drain bag is manufactured of a plastic material having higher resistance against heat than PVC.

Maasola teaches the bag for medical solutions made of a mixture of polyolefin and an elastomer (See Abstract, ln. 9-12). Since the bag material of Maasola is substantially identical to the bag material of claim 14 by its chemical composition (See Specification, page 4, [0034], ln. 27-30), the resistance against heat is inherent, as per In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the package of Dadson/ Lee with the drain bag manufactured of a plastic material having higher resistance against heat than PVC, as taught by Lee in order to make the bag compatible with the steam sterilization process.

41. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson et al. (US 5,053,003) in view of Lee (US 4,999,885), as applied to claim 27 above, and further in view of Shang et al. (US 2002/0115795).

Dadson in view of Lee disclose the claimed invention discussed above, but do not expressly disclose the method including the step of exposing the package for autoclave sterilization.

Shang teaches the step of placing (exposing) the tube set in a steam autoclave.

All the elements of the claimed invention are known in the art. One skilled in the art could have combined the known elements by known means, yielding the predictable result of the autoclave sterilization process. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Dadson/ Lee with the step of placing (exposing) the tube set in a steam autoclave, of Shang in order to provide the method with the sterilization process known in the art.

### ***Conclusion***

42. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Treyger/

Examiner

AU 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761